UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,886	07/24/2003	Robert R. Schmidt	UF-155CD3	5539
	7590 02/16/200' [K LLOYD & SALIWA	EXAMINER		
A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		02/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/627,886	SCHMIDT ET AL.				
Office Action Summary	Examiner	Art Unit				
	Anne R. Kubelik	1638				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI	I.  lely filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on 29 No.     This action is FINAL. 2b) ☐ This     Since this application is in condition for allowar closed in accordance with the practice under E.	action is non-final. nce except for formal matters, pro					
Disposition of Claims						
4) ⊠ Claim(s) 1-28 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-5,8-10 and 12-28 is/are rejected. 7) ⊠ Claim(s) 6,7 and 11 is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.					
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 10.	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite				

Application/Control Number: 10/627,886 Page 2

Art Unit: 1638

## **DETAILED ACTION**

1. Claims 1-28 are pending. It is noted that claim 11 was omitted in the originally field claims, and the claims are renumbered accordingly.

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. The terminal disclaimer filed on 29 November 2006 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent No. 5,879,941 has been reviewed and is accepted. The terminal disclaimer has been recorded.
- 4. The rejection of claims 1-4, 7-8, 10-14, 22 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 of U.S. Patent No. 5,879,941 is withdrawn in light of Applicant's filing of a terminal disclaimer.
- 5. The rejection of claims 21-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's arguments.

## Claim Rejections - 35 USC § 102

6. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 May 2006. Applicant's arguments filed 29 November 2006 have been fully considered but they are not persuasive.

Art Unit: 1638

Long et al teach a method of increasing nitrogen metabolism in plant cells by transformation with a construct encoding a bacterial glutamate dehydrogenase, which would inherently increase the assimilation of inorganic nitrogen (in the form of ammonium) into organic nitrogen. The GDH is operably linked to a chloroplast transit peptide and the construct comprises a polyadenylation sequence. The coding sequence has been altered to use plant-favored codons. The transformed cells would inherently have increased biomass or carbon/nitrogen levels.

Applicant urges that Long et al is not enabling and fails to provide the artisan with any expectation of success, only an invitation to experiment, as no details are provided by way of DNA sequence information, plasmid source, restriction enzyme information, source organism for the gene, transformation vector or target plant species (response pg 6-7).

This is not found persuasive because plant transformation, transformation vectors and which restriction enzymes can be used to clone DNAs into them, were well-known and standard in the art at the time of publication; see, for example, all the references dating from the 1980's cited in the instant specification, in the paragraph spanning pg 14-15. Bacterial GDH's were also well-known in the art. It is noted, however, that Applicant claims a plant transformed with a nucleic acid encoding a bacterial GDH, but the specification does not teach the sequence of a bacterial enzyme - is Applicant also arguing that their invention is not enabled? Plant targeting sequences are well-known, as is plant codon optimization.

Applicant urges that Long et al do not tell whether nitrogen metabolism was altered (response pg 7).

Application/Control Number: 10/627,886 Page 4

Art Unit: 1638

This is not found persuasive because the claims are drawn to either increasing or decreasing nitrogen metabolism. Long's process would inherently modify nitrogen metabolism. The instant specification shows that observable effects would be obtained.

Applicant urges that Long discloses none of their starting materials and none of the conditions under which the processes were performed (response pg 7).

This is not found persuasive because the starting materials and processes were well-known in the art.

## Claim Rejections - 35 USC § 103

7. Claims 1-5, 8-10, 12-17 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 May 2006. Applicant's arguments filed 29 November 2006 have been fully considered but they are not persuasive.

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation of a gene encoding GDH.

Long et al disclose a method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH, as discussed above. Long et al do not disclose regeneration of those cells into whole plants.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH as taught by Long et al, to regenerate those cells into

Art Unit: 1638

plants. One of ordinary skill in the art would have been motivated to do so to evaluate the performance of the plants in the field.

Applicant urges that Long only provides a suggestion to experiment and lacks specifics, is not enabling and an expectation of success (response pg 7-8).

This is not found persuasive. Plant transformation and the starting materials were well-known in the art, as discussed above. Only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988). Applicant presented no arguments as to why one would not expect success from Long's teachings, and cannot, given the effects Applicant obtained.

8. Claims 1-3, 5, 8, 10, 12-14, 16, 18-22 and 26-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi et al (US Patent 6,107,547, filed October 1994). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 May 2006.

Applicant's arguments and the Declarations of Drs. Schmidt and Miller, all filed 29 November 2006 have been fully considered but they are not persuasive.

Applicant urges that the grant proposals submitted with the declarations are from before the October 1994 filing date of '547 (response pg 8).

This is not found persuasive because both the Declarations say that that invention was conceived prior to 13 April 1995, not October 1994. The dates on the grant proposals have been redacted, so they cannot make up for that deficiency in the Declarations. Thus, '547 remains available as a reference against the claims.

Application/Control Number: 10/627,886 Page 6

Art Unit: 1638

9. Claims 1-5, 8-10 and 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi et al (US Patent 6,107,547, filed October 1994) in view of Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 May 2006. Applicant's arguments and the Declarations of Drs. Schmidt and Miller, all filed 29 November 2006 have been fully considered but they are not persuasive.

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation with a nucleic acid encoding a bacterial GDH and modification of the nucleic acid to use plant-favored codons.

Applicant urges that the grant proposals submitted with the declarations are from before the October 1994 filing date of '547 and Long does not make up the deficiencies (response pg 8).

This is not found persuasive because both the Declarations have April 13 1995 as the earliest date cited. The dates on the grant proposals have been redacted, so they cannot make up for that deficiency in the Declarations. Thus, '547 remains available as a reference against the claims.

10. Claims 6-7 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Conclusion

11. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D. February 14, 2007

ANNE KUBELIK, PH.D. PRIMARY EXAMINER